



Do March-in Rights Ensure Low-Cost Access to Medical Products Arising From Federally-Funded Research? A Qualitative Study

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Abstract

Context: The high cost of new prescription drugs and other medical products is an important health policy issue. A recent study of patent records revealed 153 drugs and vaccines discovered at public-sector research institutions, including government laboratories. A controversial solution in these cases is the use of government march-in rights under the Bayh-Dole Act, through which the government invokes legal rights in the patents protecting products developed from public funding.

Methods: We conducted a primary-source document review of the Bayh-Dole Act's legislative history as well as of hearings of past march-in rights petitions to the National Institutes of Health (NIH). We then conducted semi-structured interviews of 12 key experts in the march-in rights of the Bayh-Dole Act to identify the sources of the disputes and the main themes in the statute's implementation. We analyzed the interview transcripts using standard qualitative techniques.

Findings: Since 1980, the NIH has fully reviewed 5 petitions to invoke march-in rights for 4 health-related technologies or medical products developed from discoveries resulting from federal funding. Three of these requests related to reducing the high prices of brand-name drugs, one related to relieving a drug shortage, and one related to a potentially patent-infringing medical device. In each of these cases, the NIH rejected the requests. Interviewees were divided on the implications of these experiences, finding the NIH's reluctance to issue march-in rights to be evidence of either a system working as intended or of a flawed system needing reform.

Conclusions: The Bayh-Dole Act's march-in rights continue to be invoked by policymakers and health advocates, most recently in the context of new, high-cost products originally discovered with federally funded research. We found that march-in rights may select for government research licensees more likely to commercialize the results and that they can be used to extract minor concessions from licensees. But as currently designed in the statute, the march-in rights are unlikely to serve as a counterweight to lower the prices of medical products arising from federally funded research.

Table of Contents

Introduction

Glossary

Introduction

Methods

Data Sources

Qualitative Data Collection

Data Analysis

Results

The Bayh-Dole Act and March-In Rights

Outcomes of Past March-In Rights Petitions

1. *CellPro Petition for Ceprate SC (1997)*
2. *Essential Inventions Petitions for Ritonavir (2004, 2012)*
3. *Essential Inventions Petitions for Latanoprost (2004)*
4. *Fabry's Disease Patients' Petition for Fabrazyme (2010)*

Two Views of March-In Rights:

March-In Rights Work Well, Are Not Intended for Price-Setting.

"Reasonable Terms" Should Include Price, Discrepancies in Access Exist.

Discussion

Conclusion

Summary

References

Tables and Figures

Table 1: List of Experts in Bayh-Dole Act and March-In Rights Petitions

Table 2: Representative Quotations Supporting and Opposing Use of March-In Rights to Address High Prices of Health Care Products Arising from Federally Funded Research

Glossary

NIH: National Institutes of Health

FDA: United States Food and Drug Administration

HAART: highly active antiretroviral therapy

FTC: Federal Trade Commission

NIAID: National Institute of Allergy and Infectious Diseases

NICE: National Institute for Health Care Excellence

Bayh-Dole Act of 1980: U.S. Congressional legislation that formalized the process of licensing patents developed from federally funded research at U.S.-based universities to commercial entities.

March-in rights: a provision in the Bayh-Dole Act that allowed the US government to exercise its authority and cancel the exclusive license if the licensee was not taking adequate steps to commercialize or not meeting the needs of the American public.

Introduction

Research funded by US taxpayers has contributed to the development of some of the most transformative drugs available to patients, including the anticancer drug imatinib (Gleevec), tumor necrosis factor blockers like infliximab (Remicade) and etanercept (Enbrel) useful in inflammatory rheumatologic and gastroenterologic diseases, and vascular endothelial growth factor inhibitors like bevacizumab (Avastin) for cancer and eye diseases.¹ One comprehensive review of patent records found that government resources had directly contributed to the discovery of 153 marketed drugs and vaccines, including some of the most transformative medicines developed in the past 20 years.² Commercialization of products based on government investment in research was a central tenant of the Bayh-Dole Act of 1980, which allowed universities to patent the results of federally funded research and then to license these patents to commercial entities, obligating the institutions to claim those rights to promote the commercialization of the inventions.

The Bayh-Dole Act also included a controversial provision intended to ensure that the final products emerging from this government-sponsored research would be available to the public on reasonable terms. This provision was *march-in rights*, specific legal rights that the government retains for products originating with the government's financial support. Before the Bayh-Dole Act, patents obtained on federally funded work remained in the government's control, although concern grew that the government was not actively seeking licenses to develop commercial products and there was not a cohesive licensing protocol across government agencies. In the 1960s and 1970s, the National Institutes of Health (NIH) and a small number of research universities designed institutional patent agreements to transfer the patent title from the government to the universities to encourage more active development. In these agreements, the government maintained march-in rights to reclaim the invention if the licensees were not taking adequate steps to commercialize the product or meeting the needs of American consumers. Thus, to "march in" means that the government exercises its authority, takes control of the invention, and cancels the grant of an exclusive license for an invention that its funds helped develop. In doing so, the government regains the authority to relicense the intellectual property to another party. This process of contingent patent title transfer with march-in rights was formalized when the Bayh-Dole Act made the process consistent across all federal agencies.

In recent years, the possibility of exercising Bayh-Dole's march-in rights has been invoked most consistently in the context of high-cost medical products that can be traced back to scientists at public-sector research institutions working with government funds. Clinicians and policymakers continue to express concern about the prices of new drugs for cancer,³ essential genetic tests,⁴ and medical devices.⁵ In July 2013, Senator Patrick Leahy (D-Vt.) submitted another petition relating to Myriad's genetic tests for predisposition to breast and ovarian cancer after Myriad sought to block competition in the wake of the US Supreme Court's invalidation of its genetic code patents.⁶ Senator Leahy argued that the essential discoveries leading to Myriad's test were developed with government funding, yet the test was too expensive for millions of women. He believed this insufficient access could be remedied using march-in rights. In 2014, an expert economist and law professor made a similar argument related to the cost of sofosbuvir (Sovaldi),⁷ the \$1,000-per-pill treatment for hepatitis C virus sold by Gilead but originally discovered by a company founded by a faculty member at Emory University, much of whose work on the usefulness of nucleoside viral inhibitors was federally funded.⁸ In 2016, the health advocacy group Knowledge Ecology International petitioned for march-in rights use for the prostate cancer drug enzalutamide (Xtandi), which was developed with federal funding at UCLA and is priced significantly higher in the US than other comparable nations.⁵² Lastly, Representative Lloyd Doggett (D-TX) led over 50 members of the House of Representatives in sending a letter to the NIH, urging them to use march-in rights as a means to combat high prescription drug prices.⁵³ In these and other cases, some have argued that US patients are in effect paying twice, once for the research and a second time for the high prices of the end products.^{9,10}

While march-in rights were codified in the 1980 legislation, the political process leading up to the passage of the Bayh-Dole Act¹¹ left the scope of applicability of march-in rights unclear, including whether they could be used to reduce consumer prices on products originating from government-sponsored research. In the more than three decades since the Bayh-Dole Act, petitions for the government to consider march-in rights have been publicly considered only five times for four different products—and subsequently rejected each time. With such a lack of clarity about march-in rights, we sought to examine their role in the licensing and commercialization of health care-related government discoveries and whether using march-in rights is a viable strategy to address the rising costs of certain health care products. To

qualitatively characterize the viability of the march-in rights, we conducted semi-structured interviews with key experts involved in the development of the Bayh-Dole Act and the march-in rights appeals. Our goal was to determine whether march-in rights effectively ensure access to innovative medical technology in which government-funded research has played an essential role.

Two reports of this work have been previously published (Treasure et al. 2014, Treasure et al. 2015).^{12, 51}

Methods

Data Sources

We first sought all publicly available documents related to the development of the legislation. We did this by reviewing US government databases holding primary source documents concerning the Bayh-Dole Act, in addition to PubMed and the legal literature (LexisNexis).

Next we reviewed records of past hearings for the march-in rights petitions that were publicly considered by the government. We limited our search to hearings on health care technology and did not seek out potential uses of the march-in rights in other contexts such as defense, environmental policy, and aerospace.

Qualitative Data Collection

We conducted semi-structured interviews with experts, including key participants in the development of the legislation and the disposition of past petitions. Such qualitative research can be useful when investigating motives and behavior in a small cohort of subjects with similar experiences.¹³ The topic areas covered were Congress's intent in creating the march-in rights provision, the rationale for past march-in rights petitions, the NIH's role in evaluating march-in rights petitions, the criteria on which march-in rights petitions are evaluated, and recommendations to improve the march-in rights policy or, more broadly, the Bayh-Dole Act.

We targeted 21 potentially relevant experts in the Bayh-Dole Act and march-in rights from the fields of politics, law, business, and health care and public health. Twelve agreed to participate, with at least 2 participants representing each of the 4 main categories of expertise. All the interviews were conducted between June and August 2013 (Table 1). The median time for the telephone interviews was 46 minutes, with a range of between 21 and 64 minutes. The

two investigators took notes during the interview, recorded the interviews, and later transcribed them. The ethics review board at Harvard Medical School approved the study.

Data Analysis

To organize the data, we collected the details of the march-in rights cases and identified common keywords and themes regarding the march-in rights process. Using these keywords, we analyzed the interview transcripts using standard qualitative coding techniques.^{14,15} Based on a subset of 3 randomly selected interviews, the investigators independently developed coding schemes for organizing the data.¹⁶ The coding schemes were then compared and reconciled (NVIVO software package, QSR International, Melbourne, Australia) to produce a final coding structure that encompassed (1) Congress's original intent of the march-in rights provisions, (2) the decision and steps to file a march-in rights petition, (3) the applicability of march-in rights to the pricing and patient access issues, (4) the decision to reject a petition, and (5) recommendations for improving march-in rights.

Results

The Bayh-Dole Act and March-In Rights

The Bayh-Dole Act of 1980 instituted a government wide policy allowing academic recipients of federal funding to seek patents on inventions developed with that funding. Universities or academic medical centers were then obligated to license the patents exclusively to small business owners and nonprofit research institutions for the purpose of development.^{17,18} In 1983, the law was expanded by executive order to include large corporations.

Lawmakers also gave the government the right to “march in” and exercise its residual intellectual property rights in the invention. By marching in, the government would grant an open license on the intellectual property with the expectation that another commercial entity would be able to develop and market the product. The law spelled out 4 circumstances in which this power could be used: to reclaim an invention when the licensee had not taken, or was not expected to take within a reasonable time, effective steps to achieve practical application (Clause 1), to “alleviate health or safety needs” not being reasonably satisfied by the licensee (Clause 2), to comply with federal laws or regulations requiring some public use of the invention (Clause 3), and to remedy a licensee's failure to meet the domestic manufacturing requirement (Clause 4).¹⁹

In Clause 1, the term *practical application* is defined in 35 USC §201(f) as “establish[ing] that the invention is being utilized and that its benefits are . . . available to the public on reasonable terms.”

Any party that believes a patent license holder has not met 1 of the 4 criteria can submit a march-in request to the appropriate US government agency, which, in the case of health care products, is usually the NIH. After receiving a petition, the agency considers whether to initiate the march-in proceedings. The process begins with an official notice sent to the licensee, who then has 30 days to respond. If the response includes a dispute over the charges, a fact-finding process is conducted that “shall be as informal as practicable and be consistent with principles of fundamental fairness,” including such principles as the right of counsel.²⁰ The contractor has the right to appeal to the federal courts a decision to exercise march-in rights. By contrast, petitioners do not have the right to appeal the decision to not exercise march-in rights.²¹

Outcomes of Past March-In Rights Petitions

CellPro Petition for Ceprate SC (1997). The first time that march-in rights were seriously considered arose out of a dispute between a start-up biotechnology company, CellPro, and Baxter Healthcare Corporation, a large medical products manufacturer. A pediatric oncologist, Curt Civin, and his colleagues at the Johns Hopkins School of Medicine discovered the technology at issue. Conducting research in 1981 funded by the National Cancer Institute, other foundation grants, and institutional support, Civin and his team developed a series of monoclonal antibodies against an antigen family (CD34) on undifferentiated stem cells. One of those antibodies was IgG myeloid-10 (My-10). The antibody was potentially useful in treating hematologic malignancies like leukemia because it could help separate undifferentiated stem cells from cancerous descendant cells during a bone marrow transplant. Johns Hopkins filed a patent application in 1984, which was granted for the My-10 antibody and all other antibodies that recognize the CD34 antigen. According to Civin, “We patented the antibody itself and the whole class of antibodies against CD34. We patented the antigen. We patented the cells and we patented the procedure for the technology for immunopurifying hematopoietic stem cells from the bone marrow.”²² Johns Hopkins subsequently licensed these patents to Becton-Dickinson & Company.

The march-in rights controversy arose because after Civin's discovery of My-10, scientists at the Fred Hutchinson Cancer Research Center in Seattle created an IgM monoclonal antibody against CD34, called 12-8, that recognized a CD34 binding site distinct from My-10's binding site. The 12-8 antibody was published in 1986 but not patented.²³ The 12-8 antibody was useful in a process developed and patented by Hutchinson scientist Ronald Berenson to purify CD34-positive stem cells using the proteins biotin and avidin. Berenson's technology formed the basis for creating CellPro, which developed the technology into the Ceparate SC tool for separating bone marrow cells.

CellPro knew early on that the Hopkins patents existed, although it received legal counsel that the Hopkins patents were invalid because they were too broad, covering antibodies to CD34 that Civin did not discover, and because they were publicly disclosed more than a year before the application. Nonetheless, CellPro sought licenses for the patents, first from Becton-Dickinson and then in January 1992 from Baxter, to which Becton-Dickinson had exclusively sublicensed the patents. Baxter offered a nonexclusive license to CellPro for a greater royalty than it received from other licensees, perhaps because Baxter saw CellPro as a potential competitor. The companies could not reach agreement, and CellPro preemptively sued to invalidate the Civin patents in April 1992.²⁴ CellPro's Ceparate SC was approved by the US Food and Drug Administration (FDA) in 1996.

In March 1997, as the years of patent litigation were reaching their conclusion, CellPro requested that the NIH assert its march-in rights and grant an open license to the Civin My-10 patents. CellPro cited Clause 1 (to reclaim an invention that had not been developed or commercialized in a reasonable length of time) and Clause 2 (to alleviate health or safety needs not being reasonably satisfied by the licensee) as the bases for its petition. CellPro pointed to the long delays in Baxter's development, the licensing terms that Baxter offered to it, and the fact that it had an approved and marketed technology. By contrast, Baxter's Isolex had only recently filed for FDA approval, in February 1997. CellPro supported its claims by pointing to Johns Hopkins's controversial patents, claiming, "CellPro does not use the My-10 antibody discovered by Dr. Civin. It is only because the patent claims were written too broadly . . . that there is even an issue." After the petition was filed, former Senator Birch Bayh (D-Ind.), cosponsor of the Bayh-Dole Act, wrote a letter to the NIH supporting CellPro's request for march-in rights use "to ensure that an important new medical product will be available for use in this country."²⁵

The NIH investigated the matter in detail to determine whether Baxter had failed to take, or was not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention (Clause 1) and whether a public health or safety need was not reasonably satisfied (Clause 2). The NIH concluded that Baxter had a promising product in development and ultimately secured a promise from the company to allow Ceprate on the market until Isolex was approved by the FDA (which occurred in 1999). Thus, in August 1997, the NIH did not initiate the formal proceedings to invoke march-in rights. The NIH remarked that it was wary “of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally-funded medical technologies.”²⁶

The NIH’s decision was a final blow to CellPro, which had received in the previous month a federal district court decision upholding Hopkins’s patents and finding CellPro guilty of willful patent infringement.²⁷ CellPro paid a penalty of more than \$15 million, was forced to file for bankruptcy, and went out of business. No entity purchased the rights to the Ceprate system out of bankruptcy, and Baxter later withdrew Isolex from the market.

Essential Inventions Petitions for Ritonavir (2004, 2012). The second petition in our review was submitted in 2004 by Essential Inventions, a nonprofit organization. The petition concerned ritonavir, an HIV protease inhibitor. Ritonavir was developed partially through a \$3.5 million grant from National Institute of Allergy and Infectious Diseases (NIAID) to Abbott Laboratories from 1988 to 1993. The objective of the grant was to investigate whether medicines could be created to block HIV protease enzymes and inhibit the spread of AIDS. Abbott received this grant under the National Cooperative Drug Discovery Group for AIDS, a federally chartered program created in response to the HIV/AIDS health crisis in the 1980s. The purpose of the funding awarded through this program was to promote synergy among government, industry, and academic laboratories to translate basic research findings regarding HIV into novel antiretroviral therapies. According to Abbott’s principal investigator, this grant “catalyzed the development of the antiretroviral program.”²⁸

The Abbott scientists’ work was highly successful, and the FDA approved ritonavir in 1996. It was originally prescribed as a component of highly active antiretroviral therapy (HAART), even though the drug’s adverse effects—gastrointestinal symptoms, paresthesias, and elevated serum triglycerides—greatly limited its use.²⁹ The viability of ritonavir in the

marketplace, however, was saved by another characteristic of the drug: its ability to work as a pharmacokinetic enhancer of other protease inhibitors. Even at a very low dose, ritonavir slowed the cytochrome P450-3A4 enzymatic system in the liver. Physicians began using, and Abbott began promoting, low-dose ritonavir dosing schedules that allowed it to potentiate the activity of other protease inhibitors used in HAART—most of which were metabolized in the same enzymatic cascade—while avoiding ritonavir’s side effects. In 2000, Abbott received approval for a new protease inhibitor, lopinavir, in a fixed-dose combination pill with low-dose ritonavir, which it called Kaletra. Abbott did not market stand-alone lopinavir.³⁰

The controversial move leading to the march-in case occurred in 2004. In prior years, Abbott had set a price for ritonavir of \$2.14 a unit, in line with the other protease inhibitors. But in 2004, Abbott abruptly increased ritonavir’s price for US consumers to \$10.71 a unit, raising the annual cost of the drug from about \$9,000 to \$50,000. Yet, Abbott did not similarly adjust the price of Kaletra, even though it included ritonavir. As a result, Kaletra became the least expensive protease inhibitor regimen for US patients that included the ritonavir-boosting supplement.

The march-in request for Abbott invoked Clauses (1) and (2) in the Bayh-Dole Act and specifically claimed “that the patent owner charges unreasonable prices for ritonavir, harming the public.”³⁰ Essential Inventions argued that by raising the price to such a degree, which created barriers to access the drug, Abbott harmed HIV patients taking ritonavir in conjunction with other protease inhibitors as part of HAART. In particular, the higher drug prices reduced patients’ adherence, which is essential in HIV regimens to prevent resistance. The company also argued that Abbott acted anti-competitively by compelling patients to switch to the fixed-dose Kaletra even if another protease inhibitor was a better fit. Last, Essential Inventions saw this petition as a way to start addressing a broader pricing issue, that products resulting from “government-funded investments are routinely being priced higher in the United States than they are in foreign countries.”³⁰

After hearing some preliminary testimony from relevant parties—including Senator Bayh, who this time argued against the exercise of march-in rights—the NIH concluded that Abbott met the standard for achieving practical application of ritonavir based on the drug’s availability for sale and its widespread use by HIV/AIDS patients. The NIH concluded “that the extraordinary remedy of march-in is not an appropriate means of controlling prices . . . [that

should be] left for Congress to address legislatively” and rejected the petition. The NIH considered that the alleged anticompetitive behavior would be better reviewed by the Federal Trade Commission (FTC). Private antitrust lawsuits later filed against Abbott’s pricing schemes were dismissed in 2009. In the wake of this petition, Abbott agreed to exempt government purchasers, both federal Medicaid and state-run AIDS drug assistance programs, from the price increase. Private pharmaceutical insurance companies and hospitals thus became the main payers of the increased price.³¹ Additionally, Abbott expanded the eligibility criteria for people seeking ritonavir through its charity program.

In 2012, a second, follow-up, petition was filed for ritonavir. In it, civil society organizations argued that US consumers were being charged 400% more than other high-income countries, creating barriers to patient access and placing US employers at an economic disadvantage with overseas competitors.³² This petition was rejected in 2013. The NIH concluded that AbbVie (Abbott’s new name) had achieved “practical application of Subject Patents,” since the drug was available for use and AbbVie had started a “Patient Assistance Program” to help patients who could not afford Norvir.³³

Essential Inventions Petitions for Latanoprost (2004). Essential Inventions filed another petition concerning Pfizer’s glaucoma medicine, latanoprost (Xalatan) in 2004, shortly after it filed its ritonavir petition. Latanoprost was developed with more than \$4 million in NIH research grant funding to Laszlo Bito, then an associate professor of ocular physiology at Columbia University. During the late 1970s and early 1980s, Bito’s laboratory developed a compound that reduced abnormally elevated intraocular pressure. After successful testing in animal models, Bito realized the therapeutic potential of this compound as a treatment for glaucoma, and Columbia filed for a patent on the compound in 1982. Columbia’s patent contains specific language identifying the invention as developed under research supported by the National Eye Institute. Latanoprost was subsequently exclusively licensed from Columbia University to Pharmacia Corporation in 1983. Pharmacia was acquired by Pfizer in 2003.³⁴

The march-in petition against latanoprost claimed that the US prices of the drug were 2 to 5 times higher than in other high-income countries—invoking Clauses (1) and (2)—despite US taxpayers’ funding its early development. In 2004, a 2.5 mL bottle cost \$19.56 in Canada but \$50.99 in the United States. The petition argued that the “reasonable terms” clause implied a

reasonable price and that this discriminatory pricing was causing disparities in access, creating a public health crisis.

The NIH disagreed. It rejected the petition for march-in rights use, claiming that Pfizer met the standard for achieving practical application and reiterating its contention from the Abbott case that the march-in process should not be a means of controlling prices.

Fabry's Disease Patients' Petition for Fabrazyme (2010). In the fourth petition, patients with Fabry's disease requested an open license for agalsidase beta (Fabrazyme), the only enzyme replacement therapy approved by the FDA to treat their disease. Fabry's disease is a hereditary lysosomal storage disease characterized by a lack of alpha-galactosidase enzyme. Chronic enzyme replacement therapy can allow patients to avoid end-state renal disease, cerebrovascular damage, severe neuropathic limb pain, and cardiovascular manifestations such as left ventricular hypertrophy, heart failure, and valve abnormalities.³⁵ Agalsidase beta enzyme replacement therapy was developed by Robert Desnick and others at the Mount Sinai School of Medicine with more than \$4.1 million in NIH funding. Desnick patented the compound in 1990 and then licensed it exclusively to Genzyme, which further developed and commercialized it.

The FDA approved agalsidase beta in 2003. Another enzyme replacement therapy for Fabry's disease, agalsidase alfa (Replagal), was approved in Europe in 2001. Made by Shire, it was never submitted to the FDA for approval after the FDA granted orphan-drug status to Fabrazyme, which gave Genzyme seven years of market exclusivity from competitors seeking to market the same drug for the same condition.³⁶ After losing the race to market in the United States, Shire withdrew its product from consideration in the United States and focused on the European market.

The controversy leading to the march-in rights petition emerged from a crisis in 2009, when viral contamination in a Genzyme manufacturing facility in Massachusetts shut down production. As a result, Genzyme could produce only enough of the drug to meet 38% of the US demand, and patients had to ration their treatment. Accordingly, dosage was cut by 62%, and no new patients were allowed to start taking agalsidase beta.

In 2010, three patients with Fabry's disease petitioned the NIH to exercise its march-in rights, invoking Clauses (1) and (2). The petitioners argued that Genzyme "has not satisfied and cannot reasonably satisfy the health and safety needs of Fabry patients by rationing drugs while preventing additional sources of manufacture." Indeed, they found evidence that during the

shortage, Genzyme sent the majority of its agalsidase beta produced in US facilities to meet its obligations in Europe so that it could continue to compete with Shire's agalsidase alfa. The petitioners believed that these actions demonstrated that Genzyme was not taking steps to achieve practical application of the invention.

The NIH rejected the petition for march-in rights use on December 2, 2010, claiming that granting the petition would not “address the problem identified by the Requestors.” The NIH argued that granting an open license through march-in rights would not increase the supply of Fabrazyme in the short term. At this time, Shire offered to manufacture and market agalsidase alfa (Replagal) in the United States, since this drug's efficacy was similar to Genzyme's agalsidase beta in treating Fabry's disease in Europe. But the FDA would not approve it based on the European data alone and requested a clinical trial comparing agalsidase alfa and agalsidase beta. Neither company wanted to pursue this because of the financial cost and market-share ramifications. As the shortage continued, the petitioners filed a citizen petition, asking the FDA to approve agalsidase alfa for short-term use, but the petition was never answered. In its response to the march-in rights petition, the NIH did not directly address the potential for agalsidase alfa use in the United States. It maintained that if a company had a viable plan to obtain FDA approval for agalsidase beta during the period that Genzyme was not able to meet demand, the NIH would reconsider its decision to exercise its march-in authority. The NIH also cited Genzyme's claim that full production would return in early 2011 and stated that the NIH would monitor Genzyme's production efforts by receiving monthly reports from original licensor, Mount Sinai. Ultimately, the shortage was resolved in 2012. In July 2014, Knowledge Ecology International submitted a letter to the FTC urging it to investigate the “decision made by Shire not to compete in the US market for Fabry's disease treatments.”³⁷

Two Views of March-In Rights

Our interview results generally fell into two dominant themes with respect to the questions of how march-in rights have functioned in the past and their role in the marketplace. One group of interviewees (*‘March in Rights Work Well’*) saw march-in rights as an extreme option intended to address situations in which products were truly unavailable and as inapplicable to situations characterized by high prices alone. The other major perspective (*‘Reasonable Terms Should Include Price’*) favored applying march-in rights to help address major inequities in the cost and

availability of health care products arising from federally funded research. Table 2 presents representative quotations from each viewpoint.

March-In Rights Work Well, Are Not Intended for Price-Setting.

One of the two prevailing themes from our interviewees was that the current commercialization system under Bayh-Dole is achieving its intended purpose, as evidenced by the many products that have arisen from federally funded research since 1980. To these interviewees, the policy was intended to ensure commercialization, so that developments “were not left on the shelf,” with the march-in rights serving as a safeguard to protect against a very narrow set of highly undesirable outcomes, such as products being acquired and intentionally not developed. To these interviewees, the fact that march-in rights have never been used does not mean that the policy is not working; instead, it is evidence of a system working as intended, in that the march-in rights cast a powerful shadow over government-sponsored research, making it less likely that companies obtaining the rights to this research would conduct themselves in ways that undermined the public health. In particular, the interviewees argued that the march-in rights have empowered grantees, commonly academic centers, to engage in the oversight of licensed products that has likely led to the selection of better developers.

Those interviewees adhering to this view also pointed out that the NIH’s consideration of march-in rights petitions in the Abbott and CellPro cases led to minor concessions on the part of the rights holders, as Abbott agreed to lower the price of ritonavir for US government purchasers and Baxter agreed to let the CellPro device remain on the market until its own product was approved by the FDA. Thus, the interviewees perceived that the existence of march-in rights, even without their fulfillment, might motivate parties to uphold the public health goals of the Bayh-Dole Act.

The interviewees attributed the government’s hesitancy to intervene through march-in rights as being related to the negative ramifications of the drug and health-technology development process. They discussed the uncertainty and expense inherent in the innovation process and theorized that granting march-in rights would deter future participants from commercializing other government-sponsored research. The reason was the possibility that an exclusive license that could be broken in extreme circumstances could diminish a licensee’s confidence in acquiring the license and subsequently investing the substantial sums required to

develop the product and to conduct the clinical trials needed to bring a therapeutic to market. In addition, the development of a marketable product from licensed patents inevitably generates a considerable amount of know-how leading to more patents that would not be covered by march-in rights, as illustrated in the Fabrazyme march-in case. To some interviewees, these facts support the impracticality of applying march-in rights to marketed products.

The interviewees pointed to the NIH's public responses to these five march-in cases as confirmation that it has been consistent in asserting its disinclination to become a "price-setting" agency. Indeed, they argued that granting march-in rights is outside the scope of the NIH as a research-funding agency and that it does not have the institutional competence to police development contracts of its extramural grantees. As additional evidence of the potential problems that might arise were the NIH to move beyond its traditional role and regulate drug prices, two interviewees cited an episode from 1989 when the NIH adopted a "reasonable pricing clause" in its cooperative research and development agreements (CRADAs) in response to the outcry over the high price of zidovudine (Retrovir). Zidovudine was discovered by Jerome Horwitz at the Karmanos Cancer Institute in Michigan, and it was then shown to be active against HIV based on testing led by Samuel Broder at the NIH. But zidovudine was sold for \$8,000 per year by Burroughs Wellcome as the HIV epidemic spread, beyond what many patients with HIV could afford, particularly with an estimated 35% having no prescription drug insurance at the time.³⁸ The CRADA pricing policy was then eliminated in 1995 based on widespread recognition that it was causing the industry to avoid even potentially beneficial collaboration with government scientists.

In summary, the interviewees ascribing to this narrative believed that march-in rights were intended to be a tool to promote commercialization. Thus, as long as technologies on the market are being sold, even if the price is somewhat higher than consumers would like, the goal of the Bayh-Dole Act has been achieved. These interviewees interpreted the text of the march-in rights provision as not suggesting or insinuating that high prices justified the use of march-in rights. They often cited later comments on this issue by Senators Birch Bayh and Robert Dole (R-Kans.): "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government."³⁹

"Reasonable Terms" Should Include Price, Discrepancies in Access Exist.

The other primary perspective from the interviewees was that the march-in rights provision could reasonably be applied to address serious inequities in the prices of products originating from federally funded research. According to this view, the Bayh-Dole Act led to an increase in commercialization, and the march-in rights were established to ensure that US citizens could access the benefits of federally funded developments. Since tax dollars contribute to health care innovation both indirectly and directly,⁴⁰ the US public has the right to access these technologies under reasonable terms, which can imply reasonable prices in certain circumstances. Yet, access on reasonable terms has not always been met.

Two interviewees traced the origin of ambiguity in the “reasonable terms” language to the development of the law. The Bayh-Dole Act originally pertained to small business owners and nonprofit research institutions. It was later expanded to include large for-profit companies via an executive order from then president Ronald Reagan. This might explain why the potential for profit incentives to lead to higher drug prices was not explicitly addressed in the writing of the law, even if the discussion before the law’s passage suggested that legislators considered it to be incorporated in the act’s language.

The interviewees pointed to the outcomes of these five petitions as evidence that the system was structured so as to make it impossible to implement march-in rights in the way it might have been intended. For example, in the march-in procedure, the patent holder can appeal the granting of the request to the courts, whereas the petitioner does not have the appeal option if the petition is rejected. This asymmetry could be a deterrent to march-in rights petitions as well as to the NIH’s invoking march-in rights. Furthermore, this group of interviewees also believed that the NIH is not equipped to address and implement a request for march-in rights. The NIH does not have the capability or the human capital to perform the detailed economic analysis and regulatory navigation required to implement a march-in request. Thus, the interviewees believed that there had been clear instances in which march-in petitions should have been filed and march-in rights should have been used but that procedures favoring inaction had deterred their use.

Finally, these interviewees believed that in certain instances, the march-in rights policy should be used as a counterweight to the high prices of health care products developed from federal funding. They believe there have been multiple cases in which high-cost health technology had created disparities in access that resulted in a public health need warranting the

use of march-in rights. The march-in rights policy requires the contractor to provide the inventions “upon terms that are reasonable under the circumstance.” These interviewees believe the intention of statutory language is ambiguous and argue that if pricing affects access, the reasonable terms clause can include reasonable pricing. The US government and its people, the largest public contributor to global scientific research and development, should not be paying the world’s highest prices for drugs that it helped develop.

Discussion

Since 1980, the NIH has publicly reviewed five petitions requesting exercise of march-in rights related to four different health-related technologies or medicines developed from federal funding. In each of these circumstances, the NIH rejected the requests. Thus, since it was enacted 36 years ago, the march-in rights provision has remained unused, despite billions of dollars of government-sponsored research and the development of scores of transformative products emerging from such investments over this time.

Yet march-in rights petitions continue to be filed by policymakers and invoked by advocates, most commonly in the context of high-cost new products developed from government-funded research. In reviewing the details of past march-in rights cases and the opinions of our interviewees, we found what appears to be a solid legal basis for considering the excessively high price of a product to be a valid reason to invoke march-in rights. The legislative history of the Bayh-Dole Act and the plain language of the statute establish that the “reasonable terms” should take price into account, particularly if it is blatantly unreasonable and a key factor in limiting access to the product.⁴¹

We also found convincing arguments from our interviewees about a regulatory and political climate offering little prospect that march-in rights would be invoked to regulate pricing of a health care product developed from federal funding. Several of the previous march-in rights petitions have outlined the detrimental effects of high prices on both US consumers and the economy. Yet march-in rights were not invoked in these cases, and it is difficult to envision more compelling scenarios, outside a price so exorbitant that a majority of patients and payers could simply not afford it (a still unrealistic hypothetical situation). Furthermore, there is wide agreement on the NIH’s hesitancy to intervene: the NIH is both ill equipped to invoke a march-in

petition and wary of the potentially negative ramifications that the enactment of march-in rights under Bayh-Dole could have on future commercialization.

If policy-makers seek to use expand the existing march-in rights policy to augment use, it would require reforms at several levels. Review could be assigned to another government agency more equipped to assess market mechanisms and access discrepancies. For instance, the Federal Trade Commission has the economic expertise and capacity for analyzing market dynamics and could be poised to better evaluate the benefits and risks of exercising march-in rights.

Additionally, change could be achieved through more local action. University technology transfer offices often consider the potential public benefit of their patented products, in addition to profit for their institutions. If universities issued more nonexclusive licenses of their products, there would be less need to rely on march-in rights. Even though nonexclusive licenses may elicit lower royalty rates, they can be successful in helping bring to market essential therapeutic technologies. For instance, the Axel patents of Columbia University claimed the method for introducing foreign protein into cells, and Stanford and University of California's Cohen-Boyer patents covered methods of gene cloning and expression. Because these discoveries were made before the Bayh-Dole Act was ratified and codified universities' rights to exclusive relationships, the universities pursued numerous non-exclusive licenses instead of exclusive ones. Ultimately, many companies developed and utilized these technologies, leading to a variety of useful therapeutic products. The Axel licenses earned more than \$800 million in revenue and the Cohen-Boyer licenses earned more than \$250 million for their respective universities.⁴⁹ Although non-exclusive licensing of intellectually property has gained support among some universities researchers,⁵⁰ companies generally consider nonexclusive licenses less attractive investments. Thus, other legislative strategies may be needed to incentivize nonexclusive licensing of drugs and other products for which development was based heavily on federal support.

It is worth noting that march-in rights and nonexclusive licenses are not the only mechanisms available to public health advocates seeking to improve access or reduce high prices related to medical products arising from federally funded research. Another option might be to promote transparency in price setting. For example, recently proposed legislation in California would require manufacturers to publicly disclose their drug development costs, which could provide greater accountability and justification for pricing.⁴² Still another option—though similarly unlikely to lead to the initiation of march-in rights in the current political climate—

would be for the United States to establish an agency modeled after the United Kingdom's National Institute for Health Care Excellence (NICE) that could guide "fair" pricing through cost effectiveness analysis.

Additionally, as once suggested by Senator Ron Wyden (D-Ore.),⁴³ the NIH could establish "payback" terms for drugs or technologies developed with federally funded patents.⁴⁴ Licenses for federally funded developments between universities and commercial entities would contain royalty terms. The company would then take the development through clinical trials and FDA approval, and if the product were profitable, it would pay a small royalty to the government to allow investment in further research. The director of the NIH, Francis Collins, has endorsed this model as an acceptable alternative to an NIH-imposed oversight of prices.⁴⁵ Not only would this model allow companies to maintain pricing flexibility, but it also would provide the NIH with funding for future research.

Of course, even without the realistic prospect of invoking march-in rights, the US government maintains the power to claim access to any patented product, regardless of its funding sources, by issuing a compulsory license, in exchange for reasonable compensation.⁴⁶ This process, which in the past has provided access to items needed for warfare that nonetheless infringe on patents, can be implemented directly by executive branch agencies without congressional approval, circumventing the bureaucratic steps of the march-in rights proceedings. The last time such a measure was invoked in the context of health care products was in 2001 during the anthrax scare, when the government was seeking to stockpile the antibiotic ciprofloxacin (Cipro) and Bayer offered a high price. Faced with the threat of a compulsory license, Bayer reduced its price by 50%.^{47,48}

Conclusion

Congress passed the Bayh-Dole Act to make the fruits of publicly funded research broadly available, and included a provision for 'march-in' rights to ensure the products of the investment would be made available to patients on reasonable terms. Yet, as the US government continues to invest in basic scientific research that will ultimately lead to commercially successful medical products, debates persist over access to and the costs of such products. Can the government's march-in rights under the Bayh-Dole Act help address these concerns? Our review suggests that the answer is generally no. At least under the current regulatory structure, the NIH will not

intervene in the marketing of products that it or its grantees have helped discover, and march-in rights are not a viable strategy to address the cost of health care products developed from public funding. Based on experience to date, march-in rights may be useful only for cases in which a government-sponsored technology is licensed and then intentionally undeveloped, or for help in extracting minor concessions from licensors in extreme circumstances.

As federally funded research continues to contribute to the discovery of important new medications, policy makers will need to revisit the Bayh-Dole Act to devise a better safety net to ensure equitable access to taxpayer-funded discoveries.

Summary:

- The Bayh-Dole Act of 1980 formalized the process of universities licensing patents developed from federally funded research to commercial entities. This legislation also contained a *march-in rights* provision, whereby the US government could exercise its authority and cancel the exclusive license if the licensee was not taking adequate steps to commercialize or not meeting the needs of the American public.
- There have been 5 march-in rights petitions for 4 different products. More recently, march-in rights petitions have been invoked in the context of high-cost medical products that were developed in part with government funding. However, the NIH has rejected every march-in rights petition. To gain a better understanding of this policy, we both examined each petition and conducted semi-structured interview with key experts.
- The interviewees were split on the implications of the rejection of the march-in rights petitions, either finding the NIH's reluctance to invoke march-in rights to be evidence of either a system working as intended or of a flawed system needing reform.

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Table 1. List of Experts in Bayh-Dole Act and March-In Rights Petitions ⁵¹

Name	How Identified (expertise)	Current Position	Summary of Role
Joseph Allen	Bayh-Dole literature (politics)	President of consulting firm focused on US technology transfer	Helped draft Bayh-Dole Act as member of Senator Birch Bayh's staff
Allen Black, JD	NIH record search (law)	Private patent attorney	Key author of agalsidase beta petition
Howard Bremer, JD	NIH record search (politics, law)	Wisconsin Alumni Research Foundation (WARF), emeritus patent counsel	Helped draft Bayh-Dole Act
Curt Civin, MD	NIH record search and medical literature (health care/public health)	Professor at University of Maryland School of Medicine	Discovered the antibody technology licensed to Baxter that was the basis for the CellPro petition
Robert Cook-Deegan, MD	Medical literature (health care / public health)	Research professor, Duke University	Academic research on patents and technology transfer
James Love	Medical literature, NIH record search (health care / public health)	President of Knowledge Ecology International	Key author of ritonavir and latanoprost petitions
Barbara McGarey, JD	Medical literature (law)	General counsel for Public Health, National Institutes of Health (NIH)	Deputy director, NIH Office of Technology Transfer during the CellPro petition

Richard Murdock	Medical literature (business)	American business executive	President of CellPro at time of petition
John Raubitschek, JD	Referral (politics, law)	Attorney for Defense Procurement and Acquisition Policy Division, US Department of Defense	Helped draft regulations to implement Bayh-Dole Act
Daniel Ravicher, JD	NIH record search (law)	Executive director, Public Patent Foundation	Provided testimony related to first ritonavir petition
Mark Rohrbaugh, PhD, JD	NIH record search (law)	Director, NIH Office of Technology Transfer	Oversees office that has responsibility for reviewing march-in rights petitions
Teri Willey, MBA	Referral, NIH record search (business)	Vice president, Mount Sinai Innovation Partners	Past president, Association for University Technology Managers, helps manage agalsidase beta license at Mount Sinai School of Medicine's technology transfer office

Names are in alphabetical order. The presence of an interview source on this list does not imply endorsement of the article or its findings.

Table 2. Representative Quotations Supporting and Opposing Use of March-In Rights to Address High Prices of Health Care Products Arising from Federally Funded Research ⁵¹

Topic	Interviewees Responses Believing March-In Rights Not Intended for Price-Setting	Interviewees Responses Believing March-In Rights Applicable to Addressing High Prices
Are high prices of government-sponsored discoveries a problem?	“If you look at all the public policy issues surrounding drug pricing and access to healthcare it’s a much bigger issue. [This pricing issue] doesn’t really get solved by having a subset of inventions and healthcare products and diagnostics or treatments or vaccines that arise out of NIH-funded research.”	“We found that 13 of the 14 drugs that we looked at with government rights in them were priced higher in the United States than in any other country. . . . Pricing is a broad issue. Government funded investments are routinely being priced higher in the United States than they are in foreign countries . . . countries we compete against in the market.”
Role of government in drug pricing	“Our concern under Bayh-Dole was ‘We want to make sure these things are being used. We want to get them off the shelf. Get them out there where the taxpayers can use them.’ That was really the essence of Bayh-Dole. We had no interest at all in trying to regulate what the prices could be because that’s a whole different thing—I don’t even know how you would do that, but you certainly wouldn’t do it under a tech transfer bill.”	“The federal government should consider rising health care costs when considering march-in . . . Bayh-Dole just opened the floodgates for federal funding to private companies. But there’s got to be some measure of control over that. There are cases where it [march-in process] absolutely should be granted . . . for the purpose of making sure that the government-funded technology is efficiently and appropriately developed.”
Bayh-Dole statutory language	“‘Reasonable terms’ means reasonable terms in the license . . . pricing should not be considered.”	“What is ‘reasonable terms’? Can you imagine what kind of reasonable terms are you talking about? Charging Americans 400 times more than foreigners? The law says ‘Available to the public on reasonable terms.’ What does ‘available to the public’ mean? It means something, right?”
Feasibility of march-	“I think [march-in rights] play an	“The value of the march-in seems to

<p>in rights being invoked</p>	<p>important background role . . . primarily as a warning or potential punishment to those who would violate the statute.”</p>	<p>be almost exclusively as a negotiating tool, but nobody really thinks that it has any credibility as such a tool because nobody ever expects NIH to march-in.”</p> <p>“I also think NIH has absolutely zero competence and zero interest in getting involved in access to healthcare products and services. They’re a research agency and the whole norm of the culture at NIH is supportive research and much less about making sure that it gets incorporated equitably into the healthcare system.”</p>
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